

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Criminal No. 13-00273 (SRN/FLN)**

UNITED STATES OF AMERICA,

Plaintiff,

v.

MORAN OZ (2);

BABUBHAI PATEL (3);

LACHLAN SCOTT MCCONNELL (6);

ELIAS KARKALAS (8);

PRABHAKARA RAO TUMPATI (9);

Defendants.

ORDER

Jacqueline Blaesi-Freed, Linda I. Marks, U.S. Department of Justice, Consumer Protection Branch, 450 5th St. NW, Ste. 6400, Washington, DC 20001, and Roger J. Gural, U.S. Department of Justice, Civil Division, P.O. Box 386, Washington, DC 20044, for the United States of America.

Joseph S. Friedberg, Joseph S. Friedberg, Chartered, 701 4th Ave. S., Ste. 300, Minneapolis, MN 55415, Robert D. Richman, P.O. Box 16643, St. Louis Park, MN 55416, for Defendant Moran Oz.

JaneAnne Murray, Murray Law LLC, 310 South Fourth Ave., Ste. 5010, Minneapolis, MN 55415 for Defendant Babubhai Patel.

Marie Celine Pacyga and Ryan M. Pacyga, Pacyga and Associates, PA, 333 South Seventh St., Ste. 2850, Minneapolis, MN 55402, for Defendant Lachlan Scott McConnell.

Daniel L. Gerds, 247 Third Ave. S., Minneapolis, MN 55415, John C. Brink, 310 4th Ave. S., Ste. 1008, Minneapolis, MN 55415, for Defendant Elias Karkalas.

James E. Ostgard, Ostgard Law Office, P.O. Box 582536, Minneapolis, MN 55458, Paul Daniel Schneck, Paul Daniel Schneck, LTD, 222 South 9th St., Ste. 1600, Minneapolis, MN 55402, for Defendant Prabhakara Rao Tumpati.

SUSAN RICHARD NELSON, United States District Judge

This matter is before the Court on Defendants’ First Motion in Limine (“Defs.’ Mot.”) [Doc. No. 715]. That Motion asks the Court to exclude evidence and argument in support of the counts alleging that Defendants violated the Controlled Substances Act by distributing Fioricet without valid prescriptions and through an online pharmacy that was not properly registered. (Id.) For the reasons set forth below, Defendants’ Motion is denied.

I. BACKGROUND

Defendants are charged with a variety of offenses related to their involvement with an online pharmacy, RX Limited (“RXL”). (See Indict. [Doc. No. 5].) In relevant part, Defendants Moran Oz, Babubhai Patel, Lachlan McConnell, and Elias Karkalas,¹ are charged with violating the Controlled Substances Act (“CSA”) by: (1) dispensing a drug known as Fioricet without valid prescriptions as required by 21 U.S.C. § 829(e); (2) dispensing Fioricet through RXL and its affiliates, which were not registered with the Drug Enforcement Agency (“DEA”) as required by 21 U.S.C. § 823(f); and, (3) dispensing Fioricet through RXL, which did not display certain information on its website(s) as required by 21 U.S.C. § 831. (See Indict. at 38–41.) The Government charges that Defendants’ failures to abide by the requirements of 21 U.S.C. §§ 823(f), 829(e), and 831 constituted criminal violations of 21 U.S.C. § 841(h)(1). (See id. at 40–41.)

¹ Defendant Prabhakara Rao Tumpati joins in the Defendants’ Motion, but is not charged with any Controlled Substances Act violations. (See Indict. at 39.)

Previously, certain Defendants moved to dismiss the CSA counts based on their contention that Fioricet is not a controlled substance. (See Doc. No. 340, 377, 417.) The Court rejected this argument, found that Fioricet is a controlled substance, and denied the motion. United States v. Oz, No. 13-cr-273 (SRN/JJK), 2016 WL 1183041, at *3–6 (D. Minn. Mar. 28, 2016). Defendants now argue that the Court should exclude all evidence and argument regarding the CSA charges that Fioricet was dispensed without a valid prescription and that RXL dispensed Fioricet without being registered with the DEA because Fioricet is “explicitly exempted” from those provisions of the CSA.² (Defs.’ Mem. in Supp. of First Mot. in Limine (“Defs.’ Mem. in Supp.”) at 2–3 [Doc. No. 716].) Defendants explain that this argument is different from their previous challenge to the CSA charges because “even assuming Fioricet is a controlled substance, it is still exempt from 21 U.S.C. §§ 829 and 823 and, therefore, its distribution is authorized without regard to those statutes.” (Id. at 2.)

At a minimum, Defendants’ past and present challenges to the CSA charges are closely related. Thus, the Court incorporates its previous analysis in this opinion.

II. DISCUSSION

A. Fioricet, the Controlled Substances Act, and the Exempting Regulation

The CSA provides, in relevant part, that “it shall be unlawful for any person knowingly or intentionally . . . deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter” 21 U.S.C. §

² Defendants concede that even if the Court accepts their argument, Fioricet is not exempt from the website information requirements of 21 U.S.C. § 831 and thus the CSA charges based on a failure to post that information remain. (Def.’s Mem. in Supp. at 2, 10.)

841(h)(1)(A). Specific examples of conduct constituting a violation of § 841(h)(1)(A) include:

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 823(f) of this title (unless exempt from such registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of section 829(e) of this title;

...

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 831 of this title.

21 U.S.C. § 841(h)(2). Notably, the CSA charges against Defendants allege almost exactly the sorts of violations discussed in § 841(h)(2)(A), (B), and (E).

The CSA provides criteria for persons to be authorized to distribute and dispense controlled substances under the Act. See 21 U.S.C. § 822. Section 823 requires that practitioners, including pharmacies, that dispense Schedule III controlled substances over the internet be registered with the DEA. See 21 U.S.C. § 823(e), (f). Section 829 requires a valid prescription for controlled substances dispensed through the Internet, meaning a prescription “issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient.” 21 U.S.C. § 829(e)(1)–(2); see also id. § 829(e)(2)(B) (further defining an “in-person medical evaluation” as one that is “conducted with the patient in the physical presence of the practitioner”). Section 831 requires online pharmacies to

display certain information on their websites. 21 U.S.C. § 831(c). Failure to abide by these requirements means one is not authorized to dispense a controlled substance and subject to criminal prosecution under 21 U.S.C. § 841.

Fioricet is a combination drug consisting of acetaminophen, caffeine, and butalbital (which is a derivative of barbituric acid) and is used to treat tension headaches. (See Indict. at 7.) Butalbital is a Schedule III controlled substance. 21 U.S.C. § 812, Sch. III(b)(1). Thus, Fioricet is a controlled substance because it contains butalbital. *Id.*; *Oz*, 2016 WL 1183041 at *3–5; *United States v. Akinyoyenu*, No. CR 15-42 (JEB), __ F. Supp. 3d __, 2016 WL 4151040, at *3–4 (D.D.C. Aug. 4, 2016); *United States v. Riccio*, 43 F. Supp. 3d 301, 304–05 (S.D.N.Y. 2014); *United States v. Williams*, No. CR-10-0216-HE (01), 2010 WL 4669180, at *1 (W.D. Okla. Nov. 9, 2010), *aff’d*, 549 F. App’x 813 (10th Cir. 2013). However, this does not end the inquiry since Defendants’ argument rests on an exemption related to certain provisions of the CSA.

The DEA, through a proper delegation of authority by the Attorney General, is empowered to “exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part” of Subchapter I of the Controlled Substances Act. 21 U.S.C. § 811(g)(3). By virtue of this authority, the DEA enacted a regulation stating that certain “compounds, mixtures, or preparations that contain a nonnarcotic controlled substance [including Fioricet³] . . . have been exempted . . . from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of

³ The Exempting Regulation references 21 C.F.R. § 1308.13(c), which includes “[a]ny substance which contains any quantity of a derivative of barbituric acid or any salt thereof,” like Fioricet.

the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter *for administrative purposes only.*” 21 C.F.R. § 1308.32 (emphasis added) (hereafter, the “Exempting Regulation”).

B. Akinyoyenu and the Effect of the Exempting Regulation

Defendants argue that the Exempting Regulation negated the registration and prescription requirements of 21 U.S.C. §§ 823(f) and 829(e)—meaning that even if Defendants dispensed Fioricet without valid prescriptions and RXL lacked a DEA registration, they did not violate 21 U.S.C. § 841. (See Defs.’ Mem. in Supp. at 3–10.) In essence, Defendants claim that “[b]ecause Fioricet is exempt from the provisions of 21 U.S.C. §§ 829 (valid prescription) and 823 (DEA registration), § 841 does not prohibit distribution of Fioricet in violation of these provisions. Rather, it authorizes such distribution.” (Id. at 9–10.) This argument relies almost entirely on the analysis in a recent opinion from another federal district. (See id. at 3–10 (citing Akinyoyenu, 2016 WL 4151040).) Respectfully, this Court disagrees with the relevant portion of Akinyoyenu and thus rejects Defendants’ argument and related Motion.

In Akinyoyenu, the defendant was charged, in relevant part, with violating 21 U.S.C. § 841 for dispensing Fioricet through an online pharmacy without a valid prescription. 2016 WL 4151040 at *1–2. The defendant moved to dismiss the CSA charges. Id. at *2. First, he argued that Fioricet was not a controlled substance. Id. at *3. The Honorable James E. Boasberg (“Judge Boasberg”) rejected this argument and concluded that the Exempting Regulation, by its plain language, did not exempt Fioricet

from its general classification as a Schedule III controlled substance. Id. at *4. As described above, on this point, the Court agrees with the holding in Akinyoyenu.

Second, the defendant argued that even if Fioricet was a controlled substance, distributing it without a prescription was not criminal because the Exempting Regulation exempted the drug from the CSA's prescription requirement. Id. at *5. Judge Boasberg found this argument to be more persuasive. See id. at *5–11. In his view, the key issue was whether the Exempting Regulation “authorized” the distribution of Fioricet without a valid prescription under the CSA. Id. at *5.

First, Judge Boasberg noted that the CSA criminalized the distribution of controlled substances “except as authorized by this subchapter.” Id. (quoting 21 U.S.C. § 841(a)(1), (h)(1)(A)). Although the CSA does not “elucidate what is authorized[,]” Judge Boasberg found a “long trail of breadcrumbs.” Id. (emphasis removed). Specifically, Judge Boasberg concluded that the “criminal provisions” of the CSA (e.g., 21 U.S.C. § 841) were “rife with sections that lay out actions that constitute criminal offenses unless they are authorized by the *administrative* requirements” found in other parts of the statute (e.g., 21 U.S.C. §§ 823, 829). Id. (emphasis original). Thus, Judge Boasberg held that the CSA's “administrative requirements can and do authorize conduct; individual's actions within the scope of that authorization are safe from prosecution, but extracurricular activities are not.” Id. at *6.

Second, Judge Boasberg considered the scope of the authorization set forth in the Exempting Regulation. See id. at *6–10. The government relied heavily on the “for administrative purposes only” language in the Exempting Regulation to argue that

Fioricet was only administratively, not criminally, exempt from the CSA's prescription requirement. Id. at *7, 9. In other words, the government's position was that although the Exempting Regulation prevented it from administratively pursuing the defendant for dispensing Fioricet without a valid prescription, it could pursue him for criminal violations of the CSA on that basis. See id.

After concluding that "authorized" was a broad term under the CSA, Judge Boasberg held that the Exempting Regulation exempted distribution of Fioricet from the prescription requirements of 21 U.S.C. § 829. Id. at *7. Thus, he found that the defendant was "authorized" to distribute Fioricet without a prescription and could not be criminally prosecuted on this basis. Id. The unequivocal "for administrative purposes only" language at the end of the Exempting Regulation did not alter his conclusion. See id. at *7–9.

Judge Boasberg, examining the regulatory history of the Exempting Regulation, held that the "for administrative purposes only" language was a relic of a by-gone era—before the DEA's predecessor finalized the criteria for compound drugs that would be subject to the exemption. Id. at *8. Based on this understanding, he concluded that "with drug criteria finalized for almost fifty years, 'for administrative purposes only' might now very well mean nothing at all." Id. Judge Boasberg suggested that giving this language its plain meaning—exempting Fioricet from certain administrative requirements of the CSA, but not the criminal provision of the statute—would render the Exempting Regulation "practically ineffective." Id. at *9. Moreover, Judge Boasberg found that the idea that a doctor or pharmacist might be subject to criminal, but not administrative,

discipline for dispensing Fioricet without a valid prescription—and that the government would give up its administrative, but not criminal, enforcement authority—was untenable. See id. at *7, 9. Respectfully, the Court disagrees with Judge Boasberg’s conclusions about the scope and effect of the Exempting Regulation.

First, there is no need to interpret the history behind the “for administrative purposes only” phrase—the plain language is clear and unambiguous. See Lamie v. U.S. Tr., 540 U.S. 526, 534 (2004) (“The starting point in discerning congressional intent is the existing statutory text and not the predecessor statutes. It is well established that when the statute’s language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.” (citations and quotations omitted)); Contemporary Indus. Corp. v. Frost, 564 F.3d 981, 985 (8th Cir. 2009) (“[I]f the relevant text is not reasonably susceptible to more than one interpretation, we will not look beyond it unless application of the plain language will produce a result demonstrably at odds with the intentions of its drafters.” (quotations omitted)). This Court and others have all reached the same conclusion—the Exempting Regulation affects administrative, but not criminal, enforcement actions related to Fioricet under the CSA. Oz, 2016 WL 1183041 at *4 (“[B]y its plain language, the Exempting Regulation applies only to the administrative enforcement of certain parts of the CSA.”); Riccio, 43 F. Supp. 3d at 305 (“[T]he phrase ‘for administrative purposes only’ does not introduce ambiguity. On its face, an exemption ‘for administrative purposes only’ clearly cannot and does not encompass exemptions from the criminal laws.”); Williams, 2010 WL 4669180 at *1 (“[T]he exemption is expressly limited—‘for

administrative purposes only.’ The regulation does not exempt the product from the application of [the criminal provisions of the CSA].”).

This conclusion does not produce an absurd result. Instead, as the Government suggests, it represents a reasonable agency decision to preserve resources and forgo administrative enforcement while preserving the ability to address “serious criminal misconduct—such as cases where doctors authorize hundreds of drug orders a day based solely on customer-provided questionnaires over the Internet” (Gov’t’s Resp. in Opp. to Def.’s First Mot. in Limine (“Gov’t’s Resp.”) at 9 [Doc. No. 720].) This is especially true since administrative and criminal enforcement under the CSA are distinct. See Riccio, 43 F. Supp. 3d at 305–06 (“[T]he statutory and regulatory framework make clear that administrative enforcement for violations of the Controlled Substantive Act is entirely separate and distinct from criminal prosecutions like this one.” (citing 21 C.F.R. § 1301.41(b) and 21 U.S.C. § 847)); Oz, 2016 WL 1183041 at *4 (same).

Second, the regulatory history does not support the conclusion that the Exempting Regulation serves to “authorize” distribution of Fioricet without a valid prescription or through an online pharmacy that lacks DEA registration. Even assuming that the “for administrative purposes only” language originally signified the “unfinalized” status of the drugs covered by the Exempting Regulation, it has since taken on new meaning. The Exempting Regulation was amended numerous times after the drugs it covers were finalized. See 46 Fed. Reg. 10,105, 10,105 (Jan. 30, 1981) (acknowledging that the drugs covered by the Exempting Regulations were in essence finalized); 48 Fed. Reg. 10,644, 10,645 (Mar. 14, 1983); 52 Fed. Reg. 9,802 9,803 (Mar. 27, 1987) (eliminating the

phrase “until criteria are adopted” in recognition that the drugs covered by the Exempting Regulation were now finalized); 53 Fed. Reg. 10861-01 (April 1, 1988); 55 Fed. Reg. 9113-01 (March 12, 1990); 57 Fed. Reg. 23301-01 (June 3, 1992); 62 Fed. Reg. 13938-01 (March 24, 1997). In every one of these amendments, the “for administrative purposes only” language remained. This fact strongly suggests that the language was not left in the Regulation inadvertently or by virtue of negligent drafting.⁴ The only logical conclusion to draw from this history is that the DEA intended “for administrative purposes only” to mean exactly what it says—that is, while the distribution of Fioricet is exempt from administrative enforcement of certain requirements under the CSA, criminal prosecution for failure to abide by these requirements is unaffected (i.e., the Exempting Regulation does not “authorize” the distribution of Fioricet via the Internet absent compliance with §§ 823(f) and 829(e)).

Third, understanding the Exempting Regulation to “authorize” the distribution of Fioricet without a valid prescription would lead to an illogical result. Dispensing Fioricet without a valid prescription is criminal under the Food, Drug, and Cosmetic Act (“FDCA”). See 21 U.S.C. §§ 331(a), 333(a), 353(b); United States v. Smith, 573 F.3d 639, 650–53 (8th Cir. 2009) (holding that the prescription required by the FDCA must come in the usual course of professional practice, be for a legitimate medical purpose, and be the result of a bona fide physician-patient relationship). The Court agrees with the Government that adopting Defendants’ view of the Exempting Regulation would create

⁴ This is especially true since the Exempting Regulation is a single paragraph long, meaning it is not complex or lengthy.

“an odd regulatory regime whereby issuing Fioricet without a valid prescription is unlawful under one law regulating prescription drugs [the FDCA] and permissible under a second law regulating prescription drugs that also contain a controlled substance [the CSA].” (Gov’t’s Resp. at 10–11.)

In short, the Court holds that the Exempting Regulation means precisely what it says—those who dispense Fioricet are relieved of certain requirements under the CSA “for administrative purposes only.” Administrative enforcement actions based on the exempted CSA provisions are barred, but criminal enforcement remains unchanged. The Exempting Regulation does not authorize the distribution of Fioricet without a valid prescription or through an online pharmacy that lacks DEA registration for the purposes of criminal charges under 21 U.S.C. § 841(h)(1).⁵

III. ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED THAT:**

1. Defendants’ First Motion in Limine [Doc. No. 715] is **DENIED**.

⁵ Defendants do not explicitly argue that the rule of lenity favors their understanding of the Exempting Regulation, but Akinyoyenu raised the issue. See 2016 WL 4151040 at *9–10. Judge Boasberg found that the rule of lenity—which requires that ambiguous criminal laws be interpreted in favor of defendants—to be “particularly appropriate given the difficult an ordinary pharmacist would have in discerning [the Exempting Regulation’s] meaning.” Id. at *10. Again, this Court disagrees. First, the Exempting Regulation is difficult to understand only if one assumes that the “for administrative purposes only” language means something other than what it says or is without meaning. Second, as this Court previously held, the CSA is not unconstitutionally vague in light of the Exempting Regulation. See Oz, 2016 WL 1183041 at *7. To the extent Defendants argue that the rule of lenity should apply, the Court rejects that argument.

Dated: January 23, 2017

s/ Susan Richard Nelson
SUSAN RICHARD NELSON
United States District Judge